K093982

**510(k) Summary** JAN - 8 2010

In accordance with 21 CFR 807.92 the following summary of information is provided:

| | |
|---|---|
| Date: | October ,8,2009 |
| Submitter: | GE Healthcare, GE Medical Systems Israel, Functional Imaging<br>4 HAYOZMA St<br>TIRAT HACARMEL, 30200, ISRAEL |
| Primary Contact Person: | Eli Werner<br>Regulatory Affairs Leader<br>GE Healthcare, GE Medical Systems Israel, Functional Imaging<br>+972-4-8563666<br>+972-4-8563664 |
| Secondary Contact Person: | Laurence Bigio<br>QA site manager<br>GE Healthcare, GE Medical Systems Israel, Functional Imaging<br>+972-4-8563666<br>+972-4-8563664 |
| Device: Trade Name: | XELERIS 3 PROCESSING AND REVIEW WORKSTATION |
| Common/Usual Name: | Nuclear Medicine Workstation |
| Classification Names: | System, Image Processing, Radiological<br>Class II ;21CFR 892.2050 |
| Product Code: | LLZ |
| Predicate Device(s): | K051673<br>XELERIS 2 PROCESSING AND REVIEW WORKSTATION |
| Device Description: | XELERIS™ 3 PROCESSING AND REVIEW WORKSTATION (Xeleris 3), as a modification of its predicate device - Xeleris 2 (K051673), is a Nuclear Medicine, PET, NM/CT, and PET/CT workstation.<br><br>Xeleris 3, as a medical device, is computer workstation software used for the display, processing, archiving, printing, reporting and networking of NM, PET, NM/CT, and PET/CT studies.<br><br>Xeleris 3 runs on Microsoft Windows XP based PC workstation (color monitor, keyboard, mouse, and CD-RW for archiving), an Ethernet network connection and system software. Optional DVD device is also available.<br><br>Xeleris 3 also operates in client-server configurations.<br><br>Xeleris 3 is classified as class II medical device, complies with voluntary Digital Imaging and Communication in Medicine (DICOM) standard. |

Intended Use: The system is intended for use by Nuclear Medicine (NM) or Radiology practitioners and referring physicians for display, processing , archiving, printing, reporting and networking of NM data including planar scans (Static, Whole Body, Dynamic, Multi-Gated) and tomographic scans (SPECT, Gated SPECT, dedicated PET or Camera-Based-PET) acquired by gamma cameras or PET scanners.

The system can run on dedicated workstation or in a server-client configuration.

The NM or PET data can be coupled with registered and/or fused CT or MR scans and with physiological signals, in order to: depict, localize, and/or quantify the distribution of radionuclide tracers and anatomical structures in scanned body tissue for clinical diagnostic purposes.

Technology: The "XELERIS 3 PROCESSING AND REVIEW WORKSTATION" employs the same fundamental scientific technology as its predicate devices "XELERIS 2 PROCESSING AND REVIEW WORKSTATION (K051673)".

Determination of Substantial Equivalence: The XELERIS 3 PROCESSING AND REVIEW WORKSTATION and its applications is designed to comply with voluntary standards as detailed in Section 9, 11 and 17 of this premarket submission. The following quality assurance measures were applied to the development of the system:

Risk Analysis
Requirements Reviews
Design Reviews
Testing on unit level (Module verification)
Integration testing (System verification)
Final acceptance testing (Validation)
Performance testing (Verification)
Safety testing (Verification)

The XELERIS 3 PROCESSING AND REVIEW WORKSTATION did not require clinical studies to support substantial equivalence.

Conclusion: GE Healthcare considers the "XELERIS 3 PROCESSING AND REVIEW WORKSTATION" to be as safe, as effective, and performance is substantially equivalent to the predicate device(s) "XELERIS 2 PROCESSING AND REVIEW WORKSTATION (K051673)".

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

GE Healthcare, GE Medical Systems Israel
% Mr. Casey Conry
Senior Project Engineer
Underwriters Laboratories, Inc
1285 Walt Whitman Rd.
MELVILLE NY 11747

JAN – 8 2010

Re: K093982
Trade/Device Name: Xeleris 3 Processing and Review Workstation
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: December 22, 2009
Received: December 24, 2009

Dear Mr. Conry:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K093982 ~~[INSERT 510(k) NUMBER IF KNOWN]~~

Device Name: XELERIS 3 PROCESSING AND REVIEW WORKSTATION

Indications for Use:

The system is intended for use by Nuclear Medicine (NM) or Radiology practitioners and referring physicians for display, processing, archiving, printing, reporting and networking of NM data including planar scans (Static, Whole Body, Dynamic, Multi-Gated) and tomographic scans (SPECT, Gated SPECT, dedicated PET or Camera-Based-PET) acquired by gamma cameras or PET scanners.

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Prescription Use_X___ AND/OR Over-The-Counter Use_ _
(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K093982